



Billing Code: 4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C.

Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public.

Information about SACHRP and the full meeting agenda will be posted on the SACHRP website at: <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

DATES: The meeting will be held on Tuesday, October 16, 2018, from 8:30 a.m. until 5 p.m., and Wednesday, October 17, 2018, from 8:30 a.m. until 4 p.m.

ADDRESSES: 6700B Rockledge Drive, Bethesda, MD 20817.

FOR FUTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; e-mail address: SACHRP@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services (HHS), through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification, and/or coordination.

The SACHRP meeting will open to the public at 8:30 a.m., on Tuesday, October 16, 2018, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Stephen Rosenfeld, SACHRP Chair.

The SAS and SOH subcommittees will present their recommendations regarding the description of “key information,” as required by the revised Common Rule at §46.116(a)(5)(i). This will be followed by a discussion of recommendations of the interpretation of the revised Common Rule’s exemptions §46.104(d)(1) and (2) for HHS funded research. Lastly, the committee will continue its July discussions on the Office of Inspector General Report, July 7, 2017: “OHRP Generally Conducted Its Compliance Activities Independently, But Changes Would Strengthen Its Independence.”

The Wednesday, October 17, meeting will begin at 8:30 a.m. The SAS subcommittee will present and discuss recommendations on the interpretation of “reasonably available” at §46.408(b), as well as discuss issues surrounding payment of subjects for participation in research. Modifications to the previous day’s work will be discussed and finalized. The meeting will adjourn at approximately 4:00 p.m., October 17, 2018.

Time for public comment sessions will be allotted both days. On-site registration is required for participation in the live public comment session. Note that public comment must be relevant to topics currently being addressed by the SACHRP. Individuals submitting written statements as public comment should email or fax their comments to SACHRP at SACHRP@hhs.gov at least five business days prior to the meeting.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting.

Dated: September 14, 2018.

Julia G. Gorey,

Executive Director,

Secretary's Advisory Committee on Human Research Protections.

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